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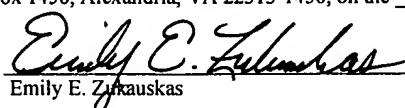
DOCKET NO.: A0848.70005US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Silence et al.
Serial No.: 10/534,348
Confirmation No.: 4929
Filed: May 9, 2005
For: SINGLE DOMAIN ANTIBODIES DIRECTED AGAINST TUMOR NECROSIS
FACTOR ALPHA AND USES THEREFOR
Examiner: Gregory S. Emch
Art Unit: 1649

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 7th day of September, 2006.


Emily E. Zukauskas

MAIL STOP AMENDMENT
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:


John R. Van Amsterdam, Ph.D., Reg. No.: 40,212
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600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: A0848.70005US00
Date: September 7, 2006
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Emily E. Zukauskas

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> | <u>Docket No.</u> |
|-------------------|--------------------|--------------------|-------------------|
| 10/534,349 | 05-09-2005 | Silence et al. | *A0848.70006US00 |

*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report or other communication from a corresponding or other International or Foreign National Application.

| <u>Serial No.</u> | <u>Mailing Date</u> | <u>Type of Communication(s)</u> |
|-------------------|---------------------|---------------------------------|
| EP 02447212.8 | April 16, 2003 | European Search Report |
| EP 03447005.4 | February 17, 2004 | European Search Report |
| PCT/EP03/07313 | March 1, 2004 | International Search Report |
| PCT/EP03/06581 | May 25, 2004 | International Search Report |

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

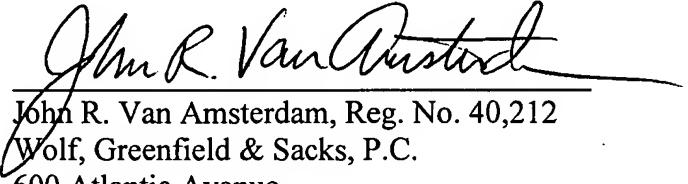
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:


John R. Van Amsterdam, Reg. No. 40,212
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: A0848.70005US00

Date: September 7, 2006

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|---|---|----|---|-----------------------------|-----------------------------------|
| <p style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> | | | | APPLICATION NO.: 10/534,348 | ATTY. DOCKET NO.: A0848.70005US00 |
| | | | | FILING DATE: May 9, 2005 | CONFIRMATION NO.: 4929 |
| | | | | APPLICANT: Silence et al. | |
| | | | | GROUP ART UNIT: 1649 | EXAMINER: Gregory S. Emch |
| Sheet | 1 | of | 2 | | |

U.S. PATENT DOCUMENTS

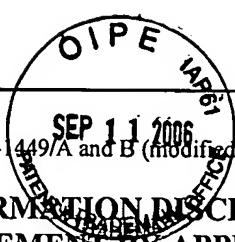
| Examiner's Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|---------------------|----------|----------------------|-----------|---|--|
| | | Number | Kind Code | | |
| | A1 | 5,976,532 | | Coller et al. | 11-02-1999 |
| | A2 | 6,419,934 | B1 | Tobinick | 07-16-2002 |
| | A3 | 6,759,518 | B1 | Kontermann et al. | 07-06-2004 |
| | A4 | 2002-0054878 | A1 | Lowe et al. | 05-09-2002 |
| | A5 | 2003-0092892 | A2 | Frenken et al. | 05-15-2003 |
| | A6 | 2006-0034833 | A1 | Silence et al. | 02-16-2006 |
| | A7 | 2006-0115470 | A1 | Silence et al. | 06-01-2006 |
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FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|---------------------|----------|-------------------------|-------------|-----------|---|--|-------------------|
| | | Office/ Country | Number | Kind Code | | | |
| | B1 | EP | 0 589 840 | A1 | CIBA Geigy AD; Tanox Biosystems, Inc. | 03-30-1994 | |
| | B2 | EP | 0 952 218 | A2 | Hoeschst Marion Roussel De GMBH | 10-27-1999 | |
| | B3 | EP | 1 002 861 | A1 | Unilever PLC | 05-24-2000 | |
| | B4 | WO | 90/10707 | A1 | Meide Petrus Hendrikus VD | 09-20-1990 | |
| | B5 | WO | 91/02078 | A1 | Peptide Technology Ltd. | 02-21-1991 | |
| | B6 | WO | 92/01787 | A1 | Cambridge Antibody Technology Ltd. | 02-06-1992 | |
| | B7 | WO | 94/04678 | A1 | Casterman | 03-03-1994 | |
| | B8 | WO | 99/09055 | A2 | Innogenetics N.V. | 02-25-1999 | |
| | B9 | WO | 99/23221 | A2 | Unilever PLC | 05-14-1999 | |
| | B10 | WO | 02/051351 | A1 | K.U.Leuven Research and Development | 07-04-2002 | |
| | B11 | WO | 02/057445 | A1 | National Research Council of Canada | 07-25-2002 | |
| | B12 | WO | 02/079781 | A1 | Heska Corporation | 10-10-2002 | |
| | B13 | WO | 2004/041862 | A2 | Ablynx N.V. | 05-21-2004 | |
| | B14 | WO | 2004/041863 | A2 | Ablynx N.V. | 05-21-2004 | |
| | B15 | WO | 2004/041865 | A2 | Ablynx N.V. | 05-21-2004 | |
| | B16 | WO | 2004/041867 | A2 | Ablynx N.V. | 05-21-2004 | |
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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|---|---|----|---|-----------------------------|-----------------------------------|
| FORM PTO-449/A and B (modified PTO/SB/08) | | | | APPLICATION NO.: 10/534,348 | ATTY. DOCKET NO.: A0848.70005US00 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | FILING DATE: May 9, 2005 | CONFIRMATION NO.: 4929 |
| | | | | APPLICANT: Silence et al. | |
| Sheet | 2 | of | 2 | GROUP ART UNIT: 1649 | EXAMINER: Gregory S. Emch |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|---------------------|---------|---|-------------------|
| . | C1 | ARBABI GHARROUDI et al., Selection and identification of single domain antibody fragments from camel heavy-chain antibodies. FEBS Lett. 1997 Sep 15;414(3):521-6. | |
| . | C2 | CORTEZ-RETAMOZO et al., Efficient tumor targeting by single-domain antibody fragments of camels. Int J Cancer. 2002 Mar 20;98(3):456-62. | |
| | C3 | DAVIES et al., Antibody VH domains as small recognition units. Biotechnology (N Y). 1995 May;13(5):475-9. | |
| | C4 | DESMYTER et al., Antigen specificity and high affinity binding provided by one single loop of a camel single-domain antibody. J Biol Chem. 2001 Jul 13;276(28):26285-90. | |
| | C5 | D'HAENS et al., Endoscopic and histological healing with infliximab anti-tumor necrosis factor antibodies in Crohn's disease: A European multicenter trial. Gastroenterology. 1999 May;116(5):1029-34. | |
| | C6 | ELS CONRATH et al., Camel single-domain antibodies as modular building units in bispecific and bivalent antibody constructs. J Biol Chem. 2001 Mar 9;276(10):7346-50. | |
| | C7 | HARMSSEN et al., Llama heavy-chain V regions consist of at least four distinct subfamilies revealing novel sequence features. Mol Immunol. 2000 Aug;37(10):579-90. | |
| | C8 | MALLENDER et al., Construction, expression, and activity of a bivalent bispecific single-chain antibody. J Biol Chem. 1994 Jan 7;269(1):199-206. | |
| | C9 | MUYLDERMANS et al., Single domain camel antibodies: current status. J Biotechnol. 2001 Jun;74(4):277-302. | |
| | C10 | ROTE et al., Antithrombotic effects of DMP 728, a platelet GPIIb/IIIa receptor antagonist, in a canine model of arterial thrombosis. J Cardiovasc Pharmacol. 1994 Apr;23(4):681-9. | |
| | C11 | SAELMAN et al., Platelet adhesion to collagen types I through VIII under conditions of stasis and flow is mediated by GPIa/IIa (alpha 2 beta 1-integrin). Blood. 1994 Mar 1;83(5):1244-50. | |
| | C12 | TANHA et al., Selection by phage display of llama conventional V(H) fragments with heavy chain antibody V(H)H properties. J Immunol Methods. 2002 May 1;263(1-2):97-109. | |
| | C13 | VALLE et al., Infliximab. Expert Opin Pharmacother. 2001 Jun;2(6):1015-25. | |
| | C14 | WARD et al., Binding activities of a repertoire of single immunoglobulin variable domains secreted from Escherichia coli. Nature. 1989 Oct 12;341(6242):544-6. | |
| | | | |

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. ___, filed ___, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

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